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February 14, 2013

FedEx: 8013 4772 5898

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-001

Document Processing Desk – 6(a)(2)
Office of Pesticide Programs
Document Processing Room S-4900
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident

Gentlemen / Ladies

In accordance with FIFRA 6(a)(2) and 40 CFR Part 159.184, we are hereby submitting a Voluntary 6(a)(2) Incident Report for an adverse incident reported to us on 2/13/2013.

Enclosed please find the following item:

1. Voluntary Industry Reporting Form 6(a)(2) Adverse Effects Incident Information (Internal ID: 1-32415381)

If you should have any questions regarding this matter, please do not hesitate to contact me at 920-326-2461 or by email at jklika@neogen.com.

Sincerely,
Hacco, Inc.

Jennifer J. Klika
Manager, Regulatory Affairs and R & D

Enclosures

JJK/dmg



Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page # 1 of 3

Row 1	Reporter name:	Submission date:	Contact person (if different than reporter)	Internal ID
Administrative Data	<i>Jeffrey Kuo, Medical Student</i>			<i>1-32415381</i>
	Address:		Address:	
	<i>Adam's County Emergency Dept Ohio</i>			
	Phone #:		Phone #:	
	<i>(937) 386-3609</i>			
	Incident Status:	Location and date of incident	Date registrant became aware of incident:	Was incident part of larger study?
	<i>New</i>	<i>Ohio Unknown</i>	<i>1/7/2013</i>	
Row 2	EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
Pesticide(s) Involved	<i>61282-46</i>			
	A.I. (s)	A.I. (s)	A.I. (s)	
	<i>Diphacinone</i>			
	Product 1 Name	Product 2 Name	Product 3 Name	
	<i>Ramik Green</i>			
	Exposed to concentrate prior to dilution? <i>NA</i>	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?	
	Formulation	Formulation	Formulation	
Row 3	Evidence label directions were not followed? <i>Yes</i>	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway))		
Incident Circumstances	Intentional misuse? <i>Yes</i>	<i>Own Residence</i>		
	Applicator certified PCO? <i>Not applicable</i>			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff)	Situation: (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating)		
	<i>See Incident Description</i>	<i>See Description Notes</i>		

1/7/2013 10:23:44 AM
Ramik Green
61282-46

HX: The caller, a fourth year medical student, reports a 40-50 YO Male had presented, transported by EMS. Current SX include somnolence. The caller states the patient can be aroused by sternal chest rub. The patient has been reported to have ingested 1/3 of a one pound bag of the product in self harm/suicide attempt. The caller was unable to provide a time line on when the ingestion took place but believed it was just preceding the call. The caller is unaware of any co-ingestion.

A: - Significant ingestion exposures that go untreated may impair the body's ability to clot blood and place a patient at risk of serious bleeding.

-There is an antidote available, if needed, called Vitamin K1. This is a longer acting anticoagulant rodenticide. Typically requiring oral administration of Vitamin K1 for 21-30 days.

-Somnolence or depression is typically not a feature of presentation unless the patient had eaten this days ago and it is related to bleeding of some form. It would certainly not be expected if the patient had just eaten this and if seen may indicate some form of co-ingestion.

-Patients ingesting more than 10 grams of this product should be evaluated further for evidence of coagulopathy. PT/PTT would be indicated

MSDS offered Fax provided 937-386-3629

Please call back with any additional questions or concerns.

The caller asks if nausea or vomiting are a feature of ingestion.

-Response: Not typically. Some products in this line may contain a bittering agent to discourage ingestion in domestic animals. It is conceivable this may upset the stomach, but the AI would not be expected to. (the caller never verified these SXS were seen)

The caller stated we may ask for him on CB but his schedule is chaotic. The attending is Dr. Mousa. The caller did not provide an identifier for the patient. He indicated history should be sufficient.

1/7/2013 11:49:15 AM client notified

1/7/2013 12:17:29 PM The fax was successfully

1/8/2013 1:44:40 PM PROSAR CB

ED reached neither Jeffrey Kuo or Dr Mousa are in. The desk was unable to give a forwarding #, voicemail, or tell when follow up may be valuable. The ED receptionist indicated they were independent contractors and the best way to get ahold of them was to obtain their personal phone numbers. The caller was unable to provide those numbers when asked.

cb reset—it is likely this case cannot be followed.

1/10/2013 1:14:16 PM PROSAR CB#2 - spoke with Jeffrey Kuo. The patient had a hx of depression and insomnia for a long time. He thinks some of the somnolence was related to sleep-deprivation. During transport to the ED the patient was hard to arouse; about an hour or so after arriving at the ED the patient was more responsive. He eventually became alert and oriented while in the ED (unknown timeframe). He was transported to a psych facility.

No known co-ingestions. The patient was unclear when he ingested the rat poison.

Closed case. Updated client.

Voluntary Industry Reporting Form for 6(a)(2) Incident Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page # 3 of 3

Demographic information Age: <i>Unknown Adult (18-64)</i> Sex: <i>Male</i> Occupation: (if relevant)	Exposure route: <i>Ingestion</i>	Was adverse effect result of suicide/homicide or attempted suicide/homicide? <i>Yes</i>	Was protective clothing worn (specify)? <i>Not applicable</i>
If female, pregnant? <i>Did not query</i>	Was exposure occupational? <i>No</i> If yes, days lost due to illness:	Time between exposure and onset of symptoms: <i>See Symptoms</i>	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). <i>HCF</i>	List signs/symptoms/adverse effects. <i>Other Neurological - Somnolence, Unable to determine;</i>		If lab tests were performed, list test names and results (If available, submit reports). <i>Not Reported</i>
Exposure data: Amount of pesticide: Exposure duration: Weight:			
Human severity category: <i>HC</i>			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
1-32415381

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